THE AGRICULTURAL MARKETING SERVICE

The U.S. Department of Agriculture's (USDA) Agricultural Marketing Service (AMS) administers programs that facilitate the efficient, fair marketing of U.S. agricultural products, including food, fiber, and specialty crops. AMS programs promote a strategic marketing perspective that adapts product and marketing practices and technologies to the issues of today and the challenges of tomorrow. In short, AMS helps make sure the U.S. marketing system remains world-class.

Market News
Farmers, shippers, wholesalers, and retailers rely on AMS Market News for up-to-the-minute information on commodity prices and shipments. Market News helps industry make the daily critical decisions about where and when to sell, and what price to expect.

Quality Standards, Grading, and Classing
AMS quality standards and grading and classing services are tools that industry uses to help promote quality and communicate that quality to consumers. Industry pays for these services, and they are voluntary, so their widespread use indicates that they are seen as valuable marketing tools.

Laboratory Testing
The AMS Science and Technology Program operates 9 "user-fee" laboratories performing numerous microbiological, chemical, and physical analyses on a host of food and fiber commodities, including processed dairy products, meat, poultry, egg products, and fruit and vegetables. This testing supports AMS purchases for the National School Lunch Program and other domestic feeding programs, troop ration specifications for the Department of Defense, foreign government food contract purchases, laboratory quality control and assurance programs, and it includes testing for aflatoxin in peanut products.

Quality Assurance
AMS develops and revises specifications that Federal agencies use in procuring food for Federal feeding programs. AMS also inspects and certifies products to the contract specifications of institutions (such as school districts, hospitals, and prisons), States, governmental agencies, and other financially interested parties who use the service.

Recently, AMS developed quality assurance and auditing services that include Hazard Analysis and Critical Control Point (HACCP)- and International Organization of Standardization (ISO)-based programs. These programs document that participating companies' operations are in compliance with either provisions of contracts or with their own standards and procedures.

Commodity Procurement
AMS purchases a variety of food products for distribution through Federal feeding programs, such as the National School Lunch and Breakfast Programs and Nutrition Program for the Elderly. In addition AMS makes emergency purchases of commodities for distribution to disaster victims. These purchases provide nutrition assistance to those who need it and also help to stabilize prices in agricultural commodity markets by balancing supply and demand. Once USDA determines

that a purchase is appropriate, AMS publicly invites bids and makes sure that the food it purchases meets quality and nutrition standards.

National Organic Program
Products labeled as organic are currently produced under a wide variety of standards, causing confusion in the marketplace. AMS is developing national standards and regulations for organically produced food and fiber which will assure consumers that agricultural products marketed as organic are consistent with these standards.

Marketing Agreements and Orders
Marketing agreements and orders are initiated by industry to help provide stable markets for dairy products, fruits, vegetables, and specialty crops. Marketing orders help to maintain the quality of produce being marketed; standardize packages or containers; and authorize advertising, research, and market development. A marketing order may also help an industry smooth the flow of crops moving to market, to alleviate seasonal shortages and gluts. Each order and agreement is tailored to the individual industry's marketing needs.

Research and Promotion Programs
National research and promotion programs are initiated by industry to improve farmers' incomes through promotion of their products. The programs are all fully funded by industry assessments. Board members are nominated by industry and appointed officially by the Secretary of Agriculture. AMS oversees the activities of the boards and approves budgets. While advertising is one part of these programs, product research and development is also a major focus. Wrinkle-resistant cotton and low-fat dairy products are just two examples of how these programs have benefitted consumers and expanded markets for producers.

Regulatory Programs: Ensuring Fair Trade in the Marketplace
AMS administers several programs that ensure fair trade practices among buyers and sellers of agricultural products.

The *Perishable Agricultural Commodities Act (PACA)* promotes fair trading in the fresh and frozen fruit and vegetable industry. Through PACA, buyers and sellers are required to live up to the terms of their contracts, and procedures are available for resolving disputes outside the civil court system.

The *Plant Variety Protection Act* provides intellectual property rights protection to developers of new and distinct seed-reproduced and tuber-propagated plants ranging from farm crops to flowers. Owners of the protected plant varieties have the exclusive right to reproduce, sell, import, and export their products in the United States for 20 years.

The *Federal Seed Act* protects everyone who buys seed by prohibiting false labeling and advertising of seed in interstate commerce. AMS also tests seed for seed producers and seed buyers on a fee-for-service basis to determine quality.

The *Agricultural Fair Practices Act* allows farmers to file complaints with USDA if a processor refuses to deal with them because they are members of a producers' bargaining or marketing association. The act makes it unlawful for handlers to coerce, intimidate, or discriminate against

producers because they belong to such groups.

Pesticide Information and Records
The AMS Pesticide Data Program (PDP) collects and compiles statistically reliable information on chemical residues found on agricultural commodities such as fresh and processed fruits and vegetables, grain, and milk. PDP is a Federal-State partnership with 10 participating States using uniform procedures to collect and test these commodities. The information gained helps form the basis for conducting dietary risk assessments and evaluating pesticide tolerances as required by the Food Quality Protection Act of 1996. The Environmental Protection Agency uses PDP data to address reregistration of pesticides. Other Federal agencies use the data to respond more quickly and effectively to food safety issues. These data also support the export of American food commodities in a competitive global marketplace and assist with integrated pest management activities.

Shell Egg Surveillance
AMS is responsible for shell egg surveillance inspections mandated by the Egg Products Inspection Act. USDA and cooperating State agencies visit egg packaging plants at least once each calendar quarter to ensure the proper disposition of "restricted eggs, " that is, those eggs that are dirty, cracked, or leaking.

Agricultural Transportation Analysis
Through its Transportation and Marketing Programs, AMS conducts research on the availability and costs of transportation services for U.S. agricultural products by railroads, trucks, inland barges, and ocean-going vessels. AMS staff also provide transportation market reports and technical assistance to agricultural shippers who are marketing their products in domestic or international markets.

Small Farms Initiatives
USDA defines small farms as those having annual gross receipts of less than $250,000, or about 94 percent of all farms in the United States. AMS is working to identify and promote the development of marketing opportunities for small farms by conducting and supporting research and providing information on farmer direct marketing activities in the public and private sectors. As part of this effort, AMS maintains a direct marketing Internet web page, updates a national farmers market directory every 2 years, and has made available a brochure and an "800" number providing information on how to set up a farmers market on Federal property. We also sponsor workshops, symposiums, focus groups, and other events where farmers, industry representatives, academics, and other experts exchange information and work together to address problems and challenges associated with small-scale farming.

Federal-State Marketing Improvement Program
Through the Federal-State Marketing Improvement Program (FSMIP), AMS provides matching funds to State departments of agriculture or other State agencies for a wide range of research and service projects aimed at improving the marketing and distribution of agricultural products. Identifying new or higher valued market outlets for farm products, finding ways to get products to consumers more efficiently, and developing new or more effective marketing service programs at the State and local level are common themes among FSMIP projects. FSMIP typically provides

support to 25-30 projects per year.

AGRICULTURAL BIOTECHNOLOGY AND AMS PROGRAMS & SERVICES

The U.S. Department of Agriculture's (USDA) Agricultural Marketing Service (AMS) administers programs that facilitate the efficient, fair marketing of U.S. agricultural products, including food, fiber, and specialty crops. A number of these programs and services have already been affected by the introduction of modern biotechnology techniques in agriculture. In some cases, biotechnology has improved our ability to provide programs or services, benefitting our customers and stakeholders with enhanced service, more cost-effective service, or both. In others cases, biotechnology is challenging the agency to develop new methods, procedures, and labor force skills to accommodate the influence of biotechnology and the changing needs of our customers.

Program Examples:

Cotton classification -- In 1998/99, almost half (48.6%) of the U.S. cotton crop was planted to transgenic varieties. Transgenic cotton has been genetically altered by the addition of genetic material to confer insect or herbicide resistence. Of the transgenic varieties planted in 1998, 22.8% were planted to herbicide resistant varieties; 17.7% to insect (budworms and bollworms) resistant varieties; and 4.6% to "stacked" varieties -- with both herbicide and insect-resistant traits. The precise impacts of these changes in the cotton marketplace are unclear, but as new varieties and traits enter the marketplace classification and grading services may become increasingly complex.

Fruits and vegetables -- At this time, biotechnology is having relatively little direct impact on the fruit and vegetable programs and services, as the main focus of innovation has been in grain and oilseed markets. Transgenic potatoes, squash, tomatoes and papayas have all been commercialized, however. The papaya marketing order committee, for example, sponsored research that lead to development of varieties resistant to the papaya ringspot virus that were made available to growers in 1997. As more of these types of products become commercialized, the marketplace may require new services from our programs.

For example, the PACA program (Perishable Agricultural Commodities Act) could be called upon to verify purchase/contract requirements relating to the use of modern biotechnology techniques. This could require new or alternative modes of inspection or verification, including development of new testing protocols. The ability to alter genetic characteristics of products may also require some changes in the ways in which we consider certain quality attributes.

Finally, if the market moves towards product differentiation based on use of modern biotechnology techniques, AMS' expertise in quality standards, quality assurance systems, and process verification programs may become increasingly important.

Dairy -- Dairy programs administers milk marketing order and dairy grading services. It is estimated that 15 percent of the U.S. dairy producers are using recombinant bovine somatotropin (rBST) to increase milk production in dairy cows.

Seed Testing -- We have adapted some routine germination tests for use in identifying varieties of several crops resistant to specific herbicides. State seed regulatory officials, the Association of American Seed Control Officials, and the Association of Official Seed Analysts have expressed support for this initiative. Our customers want and need the capability to do tests on seeds for variety identification and to determine if the biotech varieties meet the advertised claims. Customers also want and need to know if the products from these biotech varieties contain the value-added traits needed in the market place.

To the extent that the market may begin to differentiate between seed varieties based on the use of modern biotechnology techniques, our services may be called upon to an even greater extent to verify product marketing claims. The demand for such services would require development and validation of new testing and sampling protocols beyond our current work on germination testing. Any potential changes in international seed trade could also place greater demands on seed testing and verification services.

Plant Variety Protection Office (PVPO) – Biotechnology offers several techniques to improve plant genetics and breeding. The Plant Variety Protection Office (PVPO), which administers the Plant Variety Protection Act (PVPA), is receiving applications for protection for varieties carrying transgenes (generally back crosses of proven varieties with primary transgenic parents). These applications are mostly from private plant breeding companies and from public breeders such as land grant universities. Customers want more information about what varieties are protected now, how to prepare an application, and the implications of biotechnology for protection.

Molecular marker data could be used to establish plant variety distinctness and stability. The interaction of PVPO examiners with the breeding community, always essential for proper application of the PVPA, will become even more important as it becomes more common to submit molecular data as part of an application. PVPO examiners will need to be able to assess the validity of the method and the data, which will be of a highly technical nature.

AGRICULTURAL RESEARCH SERVICE MISSION AND RESPONSIBILITIES

The Agricultural Research Service (ARS) mission is to provide access to agricultural information and develop new knowledge and technology needed to solve technical agricultural problems of broad scope and high national priority to ensure adequate availability of high quality, safe food and other agricultural products to meet the nutritional needs of the American consumer; to sustain a viable and competitive food and agricultural economy; to enhance quality of life and economic opportunity for rural citizens and society as a whole; and to maintain a quality environment and natural resource base.

ARS serves a variety of customers and stakeholders, including the Department and Congress. Within USDA, ARS serves the Secretary of Agriculture, operating as the Department's research arm responding to the nation's critical agricultural challenges. ARS scientists, technicians and support personnel in laboratories, who are strategically located throughout the country, are at the disposal of the Secretary to investigate and solve technical problems that face American agriculture today.

Over the years, ARS has achieved major scientific breakthroughs which have benefitted farmers, ranchers, agribusiness, consumers, indeed all Americans. ARS is committed to continue enhancing the lives and well-being of every American as it strives to meet the new and emerging agricultural issues that are of concern to the nation.

ARS has primary responsibility to:

- Provide initiative and leadership in agricultural research.
- Conduct research on broad regional and national agricultural and related problems.
- Conduct research to support Federal action and regulatory agencies.
- Provide expertise to meet national food, food safety and environmental emergencies.
- Provide research support for international programs.
- Provide scientific resources to the Executive Branch and Congress.
- Transfer new knowledge, technologies and products developed through research to user groups.
- Acquire, preserve and disseminate food and agricultural information.

ARS serves as the lead Federal agency for agricultural research. Its responsibilities include a mandate to respond to the high priority research needs of action and regulatory agencies of the Department of Agriculture, and other Federal Departments and agencies.

ARS has the responsibility of providing research support to the action agencies because it has:

- Broadly based, cost-effective research programs.
- Highly qualified research scientists and support personnel.
- Costly, highly technical scientific equipment and specialized facilities (e.g., National Animal Disease Center, Plum Island Animal Disease Center, and unique chemical and biological testing capability for animals, plants and microorganisms).
- Flexibility to quickly redirect resources for emergency needs.
- Administrative mechanisms in place to work with universities and private industry (through cooperative research and development agreements).
- Scientific knowledge to provide research leadership in coordinating programs across USDA agencies.
- Research autonomy/objectivity to avoid conflicts of interest.

Roles and Responsibilities of the Agricultural Research Service (ARS) in Agricultural Biotechnology

ARS is involved in several biotechnology-related activities, including research, database management, intellectual property management and technology transfer, and information management and transfer. The research program incorporates biotechnology in support of the ARS mission, with activities ranging from sequencing of DNA to assessing the environmental risks of releasing genetically engineered organisms. Technology transfer (through the ARS Office of Technology Transfer) also encompasses multiple activities, including intellectual property protection, negotiation of agreements with the private sector as appropriate, and patent licensing for commercialization. Biotechnology information services are provided to the public and to all interested parties through the National Agricultural Library (NAL). The NAL staff is trained to help with special requests for information about biotechnology, and they have multiple resources at their disposal. These are also accessible through the World Wide Web on a public site maintained by NAL.

Under the broad definition of biotechnology currently used in ARS, biotechnology research is funded at $88.2 million (FY 2000). However, much of the research identified as biotechnology-related is in fact unrelated to genetic engineering (the creation, transfer, or characterization of recombinant DNA), which is the area of biotechnology of most concern to the public. This category of biotechnology research in ARS, plus closely aligned research, in FY2000 comprises $59.4 million of appropriated base funds. In addition, ARS scientists participate in numerous cooperative efforts with other scientists, including competitively awarded grants from the National Science Foundation, that substantially increase the funding of biotechnology research in ARS.

Biotechnology research in ARS is designed to fulfill the "Federal role" in advancing the public interest, particularly when other organizations are unable to fill this role. To meet biotechnology-related needs for the immediate future (5 years), while continuing to fulfill this role, will require expanded programs of research, technology transfer, and information management. Research areas of greatest priority and urgency are: (1) the use of biotechnology to expand and improve the ability to manage genetic resources, one of ARS' core responsibilities; (2) the curation of public genomic databases, a responsibility that is growing very rapidly as more genomic information becomes available; and (3) the assessment of environmental risk and the management of the deployment of products of biotechnology to minimize that risk. All of these high-priority needs are central to the role of the lead USDA agency for agricultural research.

The future will bring to the fore a number of other concerns, such as how to manage the need for privacy when data are shared among cooperating public and private organizations; the need for a public agency to generate data about biosafety and environmental risk of biotechnology; how to apply the benefits of biotechnology to areas where profit potential is limited or nonexistent; and to provide unbiased information about biotechnology and its risks to the public.

Cooperative State Research, Education, and Extension Service

About CSREES

The new Cooperative State Research, Education, and Extension Service (CSREES) is positioned for the 21st century as a dynamic change agent and international research and education network. CSREES expands the research and higher education functions of the former Cooperative State Research Service and the education and outreach functions of the former Extension Service. The result is better customer service and an enhanced ability to respond to national priorities.

- CSREES links the research and education programs of the U.S. Department of Agriculture and works with:
- Land-grant institutions in each state, territory and the District of Columbia;
- More than 130 colleges of agriculture; 59 agricultural experiment stations; 57 cooperative extension services;
- 63 schools of forestry;
- 17 1890 historically black land-grant institutions including Tuskegee University;
- 27 colleges of veterinary medicine;
- 42 schools and colleges of human sciences;
- 29 1994 Native American land-grant institutions;
- 190 Hispanic-serving institutions.

Mission

In cooperation with our partners and customers, CSREES provides the focus to advance a global system of research, extension and higher education in the food and agricultural sciences and related environmental and human sciences to benefit people, communities, and the Nation.

The CSREES mission emphasizes partnerships with the public and private sectors to maximize the effectiveness of limited resources. CSREES programs increase and provide access to scientific knowledge; strengthen the capabilities of land-grant and other institutions in research, extension and higher education; increase access to and use of improved communication and network systems; and promote informed decisionmaking by producers, families, communities, and other customers.

Focus

The heart of the CSREES results-oriented vision is to improve economic, environmental, and social conditions in the United States and globally. These conditions include improved agricultural and other economic enterprises; safer, cleaner water, food, and air; enhanced stewardship and management of natural resources; healthier, more responsible and more productive individuals, families and communities; and a stable, secure, diverse and affordable national food supply.

Programs

CSREES research, extension and education leadership is provided through programs in Plant and Animal Production, Protection, and Processing; Natural Resources and Environment; Rural,

Economic and Social Development; and Families, 4-H, and Nutrition; Partnerships; Competitive Research Grants and Awards Management; Science and Education Resources Development; and Communications, Technology, and Distance Education.

CSREES ROLES AND RESPONSIBILITIES IN AGRICULTURAL BIOTECHNOLOGY

Within USDA, the Cooperative State Research, Education, and Extension Service (CSREES) administers Federal funds for a variety of research, extension, and higher education programs related to food and agriculture. CSREES funds extramural agricultural research under both competitive research grants programs and cooperative funding programs in conjunction with state agricultural experiment stations. Agricultural research funded by these programs encompasses recombinant DNA research as well as non-recombinant approaches. The tools of modern biotechnology research, including recombinant DNA techniques, have been successfully integrated into mainstream agricultural research. CSREES has procedures in place to ensure that recombinant DNA research funded by the agency is reviewed beforehand by an institutional biosafety committee and either approved or exempted from applicable biosafety guidelines.

The agency administers funds for budgetary line items authorized by Congress and approved by the President. These include biotechnology special research grants, genome/genetics special research grants, and biotechnology facilities grants. Through its multistate research program, the agency funds a National Research Support Program on Animal Genome Research as well as transgenic animal research through various cooperative and competitive funding mechanisms. CSREES funds doctoral-level training grant programs through its Food and Agricultural Sciences National Needs Graduate Fellowship Grants Program including graduate training programs in animal biotechnology and plant biotechnology.

CSREES, along with the Agricultural Research Service (ARS), administers a competitive Biotechnology Risk Assessment Research Grants Program supported by set aside funds of 1 percent of the biotechnology research expenditures of CSREES, ARS, and the Forest Service. The purpose of the biotechnology risk assessment research program is to assist Federal regulatory agencies in making science-based decisions about the safety of introducing genetically-modified plants, animals, and microorganisms into the environment. The program has completed eight cycles of grant awards since its inception.

Under an internal innovation grant, the agency is also conducting a one-time effort to review, synthesize, and summarize published research results of biotechnology risk assessment research projects. The effort will be completed by outside scientific experts in a variety of disciplines and made available to the public as a semi-technical monograph authored by scientists and a professional science writer.

CSREES also administers a Small Business Innovative Research Program which funds grants that are competitively awarded to qualified small businesses for the purpose of supporting high quality research proposals containing advanced concepts related to important scientific problems and opportunities in agriculture that could lead to significant public benefit if the research is successful. Many of the advanced concepts and scientific problems in this program are biotechnology-related.

The National Research Initiative (NRI) Competitive Grants Program supports over $100 million of agricultural research grants. The eight major research areas of the NRI are: 1) Natural Resources and the Environment, 2) Nutrition, Food Safety, and Health , 3) Animals, 4) Pest Biology and Management, 5) Plants, 6) Markets, Trade, and Rural Development, 7) Enhancing Value and Use of Agricultural and Forest Products, and 8) Agricultural Systems Research. Over

these program areas, a significant number of grants awarded involves the approaches and methods of modern biotechnology. CSREES also participates with other agencies in interagency programs for the support of research in metabolic engineering and plant genome sequencing in *Arabidopsis* and rice.

For FY 2000, CSREES will administer a new program of over $100 million entitled the Initiative for Future Agriculture and Food Systems (IFAFS). The purpose of this Initiative is to support research, extension, and education activities across a variety of topic areas including agricultural genomics, agricultural biotechnology, food safety, food technologies and human nutrition, new uses for agricultural products, natural resource management, including precision agriculture, and farm efficiency and profitability. The IFAFS will give priority to multi-state, multi-institutional, and multi-disciplinary projects that successfully integrate research, extension, and education and/or address the concerns of small and mid-sized producers and land managers.

CSREES RESEARCH PROGRAMS

Special Research Grants
Facilities Grants
Animal Genome Research
Transgenic Animal Research
National Needs Graduate Fellowships Program
Biotechnology Risk Assessment Research Grants Program
    Innovation Research Grant - Biotechnology Risk Assessment--A review of research results
National Research Initiative Competitive Grants Program
Interagency Programs
    Arabidopsis Genome Sequencing Project
    Rice Genome Sequencing Project
    Metabolic Engineering
Small Business Innovative Research Program
Initiative for Future Agriculture and Food Systems

ECONOMIC RESEARCH SERVICE

U.S. DEPARTMENT OF AGRICULTURE

The mission of the Economic Research Service (ERS) is to improve public and private decision making on economic and policy issues related to agriculture, food, natural resources, and rural development.

ERS accomplishes its mission through conducting social science research and developing socioeconomic indicators on a broad range of topics related to USDA's goals and objectives. The ERS portfolio encompasses global commodity and food market conditions, trade restrictions, and trade agreements; farm and retail food prices, food assistance, food borne illness, nutrition, and food labeling; farm size and structural change affecting farmers and consumers; farmworker safety, agrichemical usage, and livestock waste management; sustainability, genetic diversity, and agricultural research and technology; rural amenities, rural infrastructure, and rural economic opportunities.

ERS communicates research results and socioeconomic indicators to public and private decisionmakers through published and electronic reports and articles; special staff analyses, briefings, presentations, and papers; data bases; and individual contacts. Three Agency periodicals are principal outlets for topical information and digested research studies: Agricultural Outlook, FoodReview, and RuralAmerica. Through publications, briefings, and other media, ERS provides decision makers with analytically based information that helps them attain the five goals of the Research, Education and Economics Mission area: agricultural competitiveness, food safety and security, a well nourished population, environmental quality, and a sustainable rural economy.

ERS has its offices in Washington, D.C. and a staff of approximately 525. The ERS FY 2000 budget was funded at $65.4 million. Along with the Agricultural Research Service (ARS), the National Agricultural Statistics Service (NASS), and the Cooperative State Research Education and Extension Service (CSREES), ERS is an agency of the Research, Education, and Economics mission area of USDA.

For more detailed information and a closer look at the ERS portfolio of products, visit our website at http://www.ers.usda.gov. Here you will find a wide array of Agency output from broadstroke overviews of the very latest issues to detailed data spreadsheets on a variety of topics.

ERS Programs Concerning Agricultural Biotechnology

SUMMARY

As the USDA's economic research and policy analytical arm, the Economic Research Service (ERS) is generally responsible for collecting, organizing, and synthesizing economic data and information, conducting analysis that informs short-run program and policy decisions within or by the USDA, and initiating problem-driven economic research that anticipates and addresses emerging issues in the food-agriculture-natural resources/environment-rural communities nexus.

ERS programs address the specific area of agricultural biotechnology in three ways, by:

1. Collecting farm-level data that provide statistically valid information on the adoption of genetically modified seed and related technologies in the U.S.;
2. Conceiving and carrying out a program of anticipatory research on multiple dimensions of agricultural biotechnology and its economic implications; and
3. Maintaining and utilizing the capacity to respond to requests for short turnaround analysis of and/or options for Departmental response to unanticipated events, observed market phenomena, or policy proposals concerning, affecting, or affected by agricultural biotechnology.

Data Collection

ERS annually collects financial information in conjunction with data on production practices, resource use, and production costs by specific commodities. Since 1996, questions have been included on the major survey instrument, the Agricultural Resource Management Study (ARMS) survey, regarding major field crop farmers' use of specific types of genetically modified seed. Due to the nature of the ARMS survey design, data on GMO seed adoption are linked to data on yield, pesticide use, other farm practices, and the financial characteristics of a subset of adopters and nonadopters. This is a rich source of data from which to track adoption patterns and trends, and evaluate the relationships among GMO seed technology adoption, farm characteristics, production practices, yields, and economic returns.

Preliminary evaluations based on the first three years of the data's availability may be found on the ERS Web site at:

Problem Driven Anticipatory Research

The ERS agricultural biotechnology research program is multidimensional, including explicit efforts to address: biotechnological research and development and marketing; the adoption, diffusion and agricultural market impacts of biotechnologies; international trade considerations; and consumer acceptance and environmental impacts. The key research objectives that follow represent efforts planned for or underway in FY 2000. They are being addressed both through intramural research projects, and via cooperative research agreements with academic counterparts in an array of institutions. The collective effort positions ERS as a center of excellence on the economics of agricultural biotechnology.

Key Research Objectives:

1. *Evaluate biotechnology's impacts on marketing, trade, and policy*

a. Implications for market structure and coordination
b. Impact on regional and national comparative advantage
c. International harmonization of testing protocols
d. Roles of government and costs associated with GMO-free labeling
e. Implications for grain grades and standards
f. Distributional effects across the marketing chain

1. *Assess the farm-level effects of adopting genetically modified crops (and, eventually, animals)*
   a. How do farmers benefit from GM seed technology? What adoption rates characterize GMO seed technologies? What factors affect observed adoption rates? What is the effect of GMO adoption on yields, farm profits, and pesticide use?
   b. How do farmers' adoption decisions affect the direction of private sector R&D?
   c. Do small farms adopt GMO crop varieties at different rates than larger farms?

1. *Derive implications for agricultural research policy*
   a. What is the role of public agricultural research?
   b. What impacts do intellectual property rights have on the direction and level of both private and public biotechnology R&D?
   c. How has the industrial organization of the agricultural inputs industry changed and how does this affect R&D strategies?
   d. How important are genetic resources, how should they be managed, and what impact does biotechnology have on genetic resources and biodiversity?
   e. What are the impact of vertical relationships and the potential for market power on the distribution of economic surplus in the U.S. agricultural inputs industry?
   f. What are the implications of university-industry R&D collaborations? Do these collaborations affect the direction of biotechnology research?

1. *Evaluate consumer welfare associated with products derived from genetically engineered materials*
   a. Explore consumer acceptance of biotechnology: Derive lessons from rbST.
   b. What do we know about the demand for biotech products that directly benefit consumers?

In one comprehensive initial effort, ERS is developing an Agricultural Information Bulletin entitled *Issues in Agricultural Biotechnology*, which highlights and summarizes what we currently know about many of the issues identified above. The report, undergoing editing as of February 2000, should be available before Summer 2000.

Short Turnaround Policy Analytical Input to USDA Decision Making

The availability of up-to-date economic data and information, the maintenance of staff expertise through ongoing intramural and extramural research programs, and the logical methods routinely used in conceptualizing economic phenomena, make ERS a valuable source of short turnaround policy analysis to inform program and policy decisions.

For example, ERS has estimated the cost of segregating GMO from GMO-free grain as an input to decisions on the USDA position on GMO labeling. In the Fall of 1999, ERS led an interagency effort to evaluate the potential roles of the Federal government in facilitating private market developments in grain markets segregated according to GMO traits. By March 2000, a background paper on the economics of

differentiating product markets (broadly defined; including but not limited to labeling of GMOs) will be available on the ERS Home Page.

FOREIGN AGRICULTURAL SERVICE

The Foreign Agricultural Service (FAS) is an agency of the U.S. Department of Agriculture (USDA) that represents the diverse interests of U.S. farmers and the food and agricultural sector abroad. FAS seeks improved market access for U.S. products and implements programs designed to build new markets and to maintain the competitive position of U.S. products in the global marketplace. FAS programs help U.S. exporters develop and maintain markets overseas for hundreds of food and agricultural products ranging from bulk commodities to brand-name grocery items.

FAS also carries out food aid and market-related technical assistance programs, as well as operates a variety of Congressionally mandated import and export programs. FAS helps USDA and other federal agencies, U.S. universities, and others enhance the global competitiveness of U.S. agriculture and helps increase income and food availability in developing nations by mobilizing expertise for agriculturally led economic growth.

Formed in 1953 by executive reorganization, FAS is one of the smaller USDA agencies, with a personnel strength of about 900. FAS operates worldwide with personnel located in more than 75 posts covering more than 130 countries. Its overseas staff is backed up by a team of analysts, negotiators, and marketing specialists located in Washington, D.C.

Trade offices in 12 key market countries function as service centers for U.S. exporters and foreign buyers seeking market information. U.S. agricultural trade offices and attache offices provide foreign buyers with up-to-the-minute communication with potential suppliers in the United States. They also assist U.S. exporters in launching products in overseas markets characterized by different food preferences, social customs, and marketing systems.

FAS coordinates and directs USDA's responsibilities in international trade agreement programs and negotiations, working closely with the U.S. Trade Representative's office in this effort. International trade policy experts within FAS help identify--and work to reduce--foreign trade barriers and practices that discourage the export of U.S. farm products.

In virtually every foreign market, U.S. agricultural exports are subject to import duties and non-tariff trade restrictions. Trade information sent to Washington from FAS personnel overseas is used to map strategies for improving market access, pursuing U.S. rights under trade agreements, and developing programs and policies to make U.S. farm products more competitive.

FAS collects global crop and livestock production data and import/export information provided by the attache service, U.S. agricultural traders, remote sensing systems, and other sources. FAS uses this information to prepare production forecasts and assess export marketing opportunities, as well as to track changes in policies affecting U.S. agricultural exports and imports. These analyses are used by policy makers, program administrators, farmers, exporters, and others.

FAS provides U.S. agricultural exporters with short- and intermediate-term commercial financing support through the Commodity Credit Corporation (CCC) export credit guarantee programs. These programs, the Export Credit Guarantee Program (GSM-102) and the Intermediate Export Credit Guarantee Program (GSM-103), protect U.S. exporters or U.S. financial institutions against risk if the importer's foreign bank fails to make payment. The GSM-102/103 programs are designed to expand and maintain foreign markets for U.S. agricultural commodities, and may

serve to help developing nations make the transition from concessional financing to cash purchases.

The United States is the world's largest food aid donor. The administration of U.S. food aid programs is shared by the USDA and the Agency for International Development in providing assistance to needy people around the world.

FAS ACTIVITIES IN BIOTECHNOLOGY

Market Access: FAS facilitates the acceptance by foreign governments of products derived from biotechnology approved in the United States through bilateral consultation, the provision of basic information on the U.S. regulatory processes and procedures, and the provision of technical assistance and training.

FAS hosts foreign government officials, the scientific community, the media, environmental and consumer groups to help foster a better understanding of the benefits and risks associated with agricultural biotechnology. Part of this effort has centered around informing foreign governments about the how biotechnology is currently used in U.S. agriculture. FAS has initiated, coordinated and funded a broad range of workshops and symposiums to facilitate foreign governments' understanding of biotechnology and the U.S. regulatory review process. FAS also supports this effort through regular dissemination of information to our offices overseas on different biotechnology related topics. Specific market access issues are generally addressed through FAS embassy offices and through bilateral discussions with foreign governments.

WTO Notifications: FAS has primary responsibility to ensure that all proposed biotechnology regulations notified to the WTO in accordance with the Technical Barriers to Trade (TBT) and Sanitary and Phytosanitary (SPS) agreements are reviewed and commented on with appropriate follow-up to assure that U.S. concerns are reflected in the final regulations. FAS also reviews WTO notifications to ensure that countries are living up to their WTO committments.

FAS drafts and obtains interagency clearance on official U.S. government comments on these notifications which are sent to the foreign government notifying the proposed regulation. An increasing number of these notifications address biotechnology products.

Multilateral Negotiations: FAS participates in, and helps coordinate the development of U.S. government positions for multilateral discussions directed at developing protocols, agreements, or understanding that will affect trade in agricultural biotechnology products, such as the Biosafety Protocol and the next WTO round.

Export Information: FAS provide U.S. exporters with information on foreign acceptance and import criteria for biotechnology products.

Export Promotion and Food Aid Programs: FAS is increasingly providing information about biotechnology as it pertains to these programs.

Food Safety and Inspection Service
United States Department of Agriculture

The Food Safety and Inspection Service (FSIS) is responsible for ensuring that the nation's commercial supply of meat, poultry, and egg products is safe, wholesome, and correctly labeled and packaged as required by the Federal Meat Inspection Act, the Poultry Products Inspection Act, and the Egg Products Inspection Act. FSIS activities include:

- Inspecting domestically produced poultry and livestock, as well as processed products made from them
- Inspecting imported meat and poultry as well as reviewing and monitoring the foreign inspection systems in the products' country of origin to ensure they are equivalent to the United States' system
- Continuous inspection of all liquid, frozen, and dried egg products
- Setting standards for plant facilities, product contents, processing procedures, packaging, and labeling
- Analyzing products for microbiological, chemical, and physical adulterants
- Educating consumers about foodborne illness by way of publications, educational campaigns, and a toll-free Meat and Poultry Hotline.

Food Safety and Inspection Service
United States Department of Agriculture

Biotechnology Overview

Since the mission of the Food Safety and Inspection Service (FSIS) is to assure that consumers receive safe, wholesome, and truthfully labeled meat, poultry, and egg products, biotechnology that affects these food products will have an impact on the Agency's inspection activities. Animals that are subjected to or the result of biotechnology research and slaughtered for use as human food must be inspected under FSIS experimental animal regulations (9CFR 309.17 and 9CFR 381.75). These regulations specify that approval must be obtained from FSIS before experimental animals may be presented for slaughter.

FSIS has not granted approval to slaughter any transgenic animals.

Animals Used for Research to Produce Other than Food Product

First, there are animals that are involved in genetic research that is intended primarily to produce products that are not food, such as pharmaceuticals. At present, this activity is largely experimental and the number of animals resulting from such experiments is low. Further, the emphasis is on the production of pharmaceuticals or other products rather than on the production of human food.

The experimental use of food animals to produce products other than food will likely increase. When this occurs, FSIS may begin to see a larger number of experimental animals presented for slaughter for use as food products when they are no longer useful for their primary purpose.

Animals Used for Research to Achieve Genetic Improvement

The second category of animals are those that are the subject of experiments that are intended to bring about genetic improvement, such as improved growth rate, by transgenesis. Technology that attempts to achieve this result by injecting DNA into fertilized eggs has historically resulted in only a small number of the animals being born with the genetic change. The number is sufficiently low that it probably is not yet cost-effective to develop the data required to present such animals for slaughter for food use.

There are indications from researchers, however, that the state of technology puts the creation of transgenic food animals within reach. Consequently, FSIS will likely have to address the inspection of animals from gene transfer technology that could result in the commercially viable production of transgenic animals for food uses within the next several years.

Progeny of Transgenic Animals

The third category of animals that the FSIS inspection program ultimately may have to address includes those products that result from the breeding of genetically altered animals. Development of new technologies that improve biotechnology success rates could amplify the impact of breeding transgenic animals. This includes crossbreeding of transgenic animals as well as crossbreeding transgenic animals with nontransgenic animals. As the number of transgenic animals increase, the probability that some will be intentionally or inadvertently commingled and bred with traditionally produced food animals also increases.

THE FOREST SERVICE

The FS, with an employment ceiling of 35,611 staff years in 2000, is the largest employer in USDA. The mission of the FS is to sustain the health, diversity and productivity of the Nation's Forests and Grasslands to meet the needs of present and future generations. The Natural Resource Agenda, announced in March of 1998, prioritizes four key priority areas that need the agency's and the public's immediate attention. Those are watershed health and restoration, sustainable forest management, the National Forest road system; and recreation.

National Forest System (NFS). The FS manages approximately 192 million acres of public land about 110 percent of the area of the State of Texas -- located in 44 States, Puerto Rico, and the Virgin Islands. These lands, known collectively as the National Forest System, are managed for multiple use on a sustained-yield basis using sound ecological principles to meet the needs of people today while maintaining or improving the productivity, health, resilience and vigor of forest resources for future generations. The National Forests produce diverse benefits for the American people ranging from outdoor recreation, wildlife and fish and watershed protection, to timber, forage, and minerals.

Forest and Rangeland Research and Development. The FS maintains one of the world's largest forest research organizations. FSR&D has a very broad mission to develop the knowledge and technology needed to enhance the economic and environmental values of all the nation's forests and related industries, on public and private land.

State and Private Forestry. The FS makes grants and provides technical assistance to State forestry agencies and other cooperators for protecting forest resources and improving sustainable forest management on nonindustrial private forestlands. Funding is provided for forest pest suppression on all Federal lands and cost-share assistance is made available for pest suppression on private lands. A Cooperative Fire Protection Program provides technical and limited financial support for State wildfire fighting organizations. The Forest Stewardship and Stewardship Incentives Programs provide technical and financial assistance to nonindustrial private landowners for a variety of stewardship practices including tree planting. In addition, there are several programs that provide technical and financial assistance to natural resources dependent rural communities.

THE FOREST SERVICE ROLE IN BIOTECHNOLOGY

Currently, the Forest Service operationally uses only traditional methods in plant breeding and biocontrol, both on NFS lands and through State and Private programs. Opportunities for the use of rDNA technologies are being explored by Forest Service Research and Development.

The Forest Service sees the need to continue to develop biotechnologies, both traditional and modern. The choice of an appropriate technology in a given situation depends on weighting social, economic, and environmental risks and benefits. Discussions on these technological choices should involve forest managers and landowners, scientists, and the public.

In contrast to the complexities of releasing genetically engineered organisms into the environment, using rDNA in bioprocessing provides great opportunities for increases in efficiency, and decreases in the use of energy and in pollution, with little economic or environmental risk. For example, enzymes from genetically engineered yeasts have been used in bioprocessing for conversion of wood and corn ethanol to fuel.

- **Research and Development**. R&D provides the research foundation for all aspects of forest and rangeland management. In the area of genetics, FSR has active programs in genomics, conservation genetics, population and quantitative genetics and breeding. Research includes molecular aspects of pathology and entomology, as well as genetic studies of beneficial microorganisms. Other programs address bioengineering of pulp and paper processes to improve efficiency and decrease energy use and pollution. Forest Service Research is exploring the potential uses of rDNA in the following areas: biocontrol of pest organisms and non-native invasive plants, genetic engineering of trees, bioengineering of processes, bioremediation, and is currently using it as a research tool.

- **National Forests and Grasslands**. Based on current management direction, biotechnology might be developed and used for a) biocontrol of plant, insect and disease pests, b) restoration of endangered species (e.g., American chestnut, American elm), and b) remediation of abandoned mines. For each of these cases, rDNA modified organisms might be specifically developed for situations where traditional methods had been applied without success. This would occur only with appropriate environmental documentation and public involvement.

- **State and Private Forestry** works closely with FS R&D in developing potential methods for control of forest and tree pests (e.g., Asian Longhorn beetle). In addition, cooperative forestry programs partner with the states and private landowners to provide planting material. These may also use genetic engineering at some point in the future, based on costs and benefits of the improvements, and landowner preferences.

USDA

Grain Inspection, Packers and Stockyards Administration

Backgrounder

MISSION

The Grain Inspection, Packers and Stockyards Administration (GIPSA) facilitates the marketing of livestock, poultry, meat, cereals, oilseeds, and related agricultural products and promotes fair and competitive trading practices for the overall benefit of consumers and American agriculture.

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GIPSA was established in October 1994 as part of the reorganization of the U.S. Department of Agriculture (USDA). The formation of this new agency resulted from the joining of two previously independent agencies. Today, GIPSA is part of USDA's Marketing and Regulatory Programs, which are working to ensure a productive and competitive global marketplace for U.S. agricultural products.

Our mission is carried out in two different segments of American agriculture. GIPSA's Federal Grain Inspection Service (FGIS) provides the U.S. grain market with Federal quality standards and a uniform system for applying them. Our Packers and Stockyards Programs (P&S) ensures open and competitive markets for livestock, meat, and poultry.

While both of GIPSA's program areas share a common mission of facilitating trade, the statutory bases for carrying out these programs differ fundamentally. FGIS has both service and regulatory roles. It was established to provide impartial, accurate quality and quantity measurements to create an environment that promotes fairness and efficiency. P&S, on the other hand, is a regulatory program whose roots are in providing financial protection to livestock producers and in ensuring fair and competitive markets.

The impartiality of both program areas has been essential over the years. The existence of GIPSA as an unbiased, third party entity helps ensure a fair and competitive marketing system for all involved in the merchandising of grain and related products, livestock, meat, and poultry.

Grain Inspection, Packers and Stockyards Administration

Roles and Responsibilities in Agricultural Biotechnology

Overview

In accordance with the United States Grain Standards Act (USGSA), the Grain Inspection, Packers and Stockyards Administration (GIPSA) has no authority to approve or release biotech[1] crops. GIPSA does, however, have responsibility to facilitate the fair and orderly marketing of grain and grain products, many of which will be bioengineered. To this end, GIPSA will continue to assess the market's needs; meet those needs by providing the standardized testing technology that measures new and enhanced value products; and provide that information to all in the U.S. grain marketing system, from producer to end user. To meet the market's need for impartial, professional verification of biotechnology testing technologies, GIPSA will establish a biotech reference laboratory in fiscal year 2000. This action is consistent with GIPSA's traditional role as an impartial, third party entity in the marketplace.

Authorities

In accordance with the United States Grain Standards Act, as amended (7 U.S.C. 71-87) (USGSA), and the Agricultural Marketing Act of 1946, as amended (7 U.S.C. 1621-1627) (AMA), GIPSA establishes standardized quality grades and testing methodologies. These standards are used every day by sellers and buyers to communicate the type and quality of cereals, pulses, and legumes bought and sold.

Biotechnology is affecting this program in two fundamental ways: (1) increased consumer demand for conventional crops has created a need for reliable testing methodologies to distinguish bioengineered from conventional crops; and (2) an anticipated increase of new value-enhanced traits, whether produced by conventional or biotechnological means, will create an expanded need for standardized testing methodologies to measure the enhanced quality attributes. Without standardized testing methodologies and an agreed-upon means to communicate the results, market risk will increase and the true value of future crops will be less transparent.

[1] As defined by the regulatory agencies, Animal and Plant Health Inspection Service, Food and Drug Administration, and Environmental Protection Agency.

GIPSA Initiatives

To meet the market's need for impartial, professional verification of biotechnology testing technologies, GIPSA announced on November 12, 1999, that it would establish a biotech reference laboratory. This action is consistent with GIPSA's traditional role as an impartial, third party entity in the marketplace. GIPSA has standardized numerous analytical methods to facilitate grain marketing. For example, GIPSA standardized the testing of various mycotoxins in grain by evaluating and approving commercially available test kits that measure the mycotoxin content. Grain markets rely on GIPSA as an unbiased entity to fulfill this important role in facilitating grain marketing.

Functions of the biotech reference laboratory will include:

- Evaluating and verifying the validity of analytical procedures used to detect and quantify biotechnology traits in grains and oilseeds.
- Establishing sampling procedures for use in testing genetically enhanced grains and oilseeds.
- Implementing the standardized sampling and testing methods through the official inspection and weighing program.

The reference laboratory will meet a market need to ensure the reliability of biotech crop detection methods and to facilitate information exchange, which, in turn, will decrease transaction costs and increase overall market efficiency. The lab is scheduled to open in time for the 2000 soybean and corn crop year.

GIPSA also plans to increase its ability to measure enhanced quality attributes, whether produced by biotechnology or traditional breeding methods. Analytical tests required to assure the presence or specific content of a value trait are essential to ensure the supplier (i.e., farmer, cooperative, grain facility) receives the financial benefits derived from producing grain with value-added traits. These quality tests, however, may not adapt well to field analysis and may be too costly for frequent verification analysis. As an alternative to frequent testing for value traits, GIPSA will also evaluate procedures that would ensure the preservation of a specific quality trait from farm to end-user. Industry participants adhering to the procedures, based on a GIPSA audit, would be certified as meeting the specified quality attributes.

Natural Resources Conservation Service

The Natural Resources Conservation Service (NRCS) is the lead Federal agency for conservation on private land. NRCS, formerly the Soil Conservation Service (SCS), serves the United States and its territories, commonwealths, and freely associated governments. SCS was established in 1935 to carry out a continuing program of soil and water conservation on the nation's private and nonfederal lands. The agency's first chief, Hugh Hammond Bennett, spoke eloquently for the land when he convinced Congress that soil erosion was a national menace and that a permanent agency was needed to call landowner attention to the issue.

Today, more than 6 decades later, the land - with its systems of soils, water, air, plants, and animals - still needs someone to speak for its health and well-being. That responsibility remains a challenge for NRCS. No other Federal agency speaks for the health and fate of America's private land.

NRCS, established by the Department of Agriculture Reorganization Act of 1994 (7 U.S.C. 6962), combines the authorities of the former SCS and directs sixteen additional financial or technical assistance programs for natural resource conservation and rural development.

NRCS provides conservation technical assistance through 3,000 local conservation districts to individuals, communities, watershed groups, tribal governments, Federal, state, and local agencies, and others. NRCS staff persons at the local level work with state and local conservation staff and volunteers in a partnership to assist individuals and communities to care for natural resources. NRCS also develops technical guidance for conservation planning and assistance. This technical guidance is tailored to local soil, climate, and environmental conditions. In addition to NRCS' use of its technical materials, these technical documents are widely used by governmental and non-governmental entities to ensure that conservation action is based on sound science.

NRCS is proud to be partners in conservation with America's private landowners, conservation districts, state and local governments, and others. This partnership has stabilized the American landscape, helped increase agricultural productivity, helped keep agriculture profitable, improved our environment, and improved the quality of life in rural areas. Conservation in resource management is a continuous process --- not only because of the dynamic nature of agricultural and environmental systems, but because of the sensitivity of their reaction to land use, market forces, and production technology and trends, among other factors.

Natural Resources Conservation Service
Role and Responsibilities in Agriculture Biotechnology

Natural Resources Conservation Service (NRCS) relies on many partners to help set conservation goals, to work with people on the land, and to provide assistance. Its partners include conservation districts, state and federal agencies, agricultural and environmental groups, professional societies, and a large cadre of volunteers (the NRCS Earth Team).

The strength of NRCS is its workforce. Most of its employees serve in USDA's network of local, county-based offices. Other employees are at state, regional, and national offices where they provide technology, policy, and administrative support. The majority of NRCS' employees work with private landowners and users through the USDA network of local, county-based offices. These professionals have both technical expertise and field experience to help farmers and ranchers address their natural resource challenges while maintaining or improving their economic viability. About three-fourths of the technical assistance NRCS provides goes to help farmers and ranchers develop conservation systems uniquely suited to their land and individual ways of doing business. NRCS' clientele includes corporate farms and ranches as well as the smallest of small farms. Over the past 15 years, NRCS has provided assistance to over 1.9 million individual producers through its programs.

Because biotechnology is a production input, NRCS must account for any client's desire to apply biotechnology just as it must account for application of other production technologies. NRCS' assistance must take into account the type of operation and management inputs that are being implemented whenever planning assistance is offered. NRCS's technical assistance is both diagnostic and prescriptive; therefore, the indications and contraindications of particular production inputs must be factored into recommendations made to the NRCS client based on the client's individual situation.

How will biotechnology affect conservation plans? NRCS foresees an increased demand from clients for information about biotechnological applications being used within their immediate vicinity. NRCS and other USDA extension services might, for example, provide information or recommendations if there is a request for help in designing effective practices to address pollen flow concerns. Some biotechnology products in the field will increase the complexity of planning considerations for producers and for NRCS and will, therefore, offer new challenges as NRCS provides assistance to NRCS clients.

Will biotechnology affect NRCS' role at the local level? USDA provides programs to a wide variety of land users who practice agriculture in many ways in relationship to the land, their neighbors, and their markets. Biotechnology has the potential to change these relationships in fundamental and, in some cases, unknown ways, and obviously not all producers accept or welcome these changes. As a major USDA presence at the county level, NRCS can expect to be questioned by producers and consumers alike about biotechnology products. NRCS expects to be called on to provide information about how biotechnology products are produced, their benefits, concerns regarding any potential management or environmental effects, as well as methods to avoid or mitigate those effects.

Office of Risk Assessment and Cost-Benefit Analysis

The Office of Risk Assessment and Cost-Benefit Analysis (ORACBA) was established by the Federal Crop Insurance Reform and Department of Agriculture Reorganization Act of 1994 (P.L. 103-354). ORACBA began operation on April 15, 1995, in USDA's Office of the Chief Economist. ORACBA's primary role is to ensure that major regulations proposed by USDA are based on sound scientific and economic analysis. A major regulation concerns human, health, safety or the environment and has an annual economic impact of at least $100 million in 1994 dollars. For such regulations, the Reorganization Act requires USDA to conduct a thorough analysis that makes clear the nature of the risk, alternative ways of reducing it, the reasoning that justifies the proposed rule, and a comparison of the likely costs and benefits of reducing the risk.

ORACBA provides guidance and technical assistance, coordinates risk analysis work across the Department, and certifies that statutory requirements are met. Risk assessments and cost-benefit analyses should be based on sound scientific, technical, economic, and other data. The analysis should provide a clear understanding of the hazards being addressed, the probability of occurrence, and the associated level of uncertainty. The costs associated with proposed regulation and reasonable alternatives should be compared to their benefits, including those related to the reduction or prevention of risk. In short, the analysis should communicate to policy officials and the public what is known and not known about the risk.

ORACBA assists agencies proposing major rules by identifying resources for technical assistance and other types of support for conducting a risk assessment. When risk assessment expertise is not available from within USDA, ORACBA works with agencies to identify sources in other parts of the government, academe or other consultants. External peer review of some of these risk assessments is also organized by ORACBA.

ORACBA established education and training programs that have been critical for improving risk analyses and enhancing USDA’s capacity for conducting sound risk assessments. ORACBA sponsors workshops, develops short courses, and hosts a monthly risk forum. Educational and training activities sponsored by the office bring together risk assessors from universities and the private sector, as well as from other Federal agencies.

As the only central group in USDA dealing with risk analysis, ORACBA receives numerous requests for collaboration, interaction, training, and other support. Two categories of support are particularly important. First when an issue arises involving two or more agencies within USDA, the need for a risk assessment to guide joint decision-making is apparent. ORACBA is currently fulfilling this function for several issues. Second, USDA interacts with other federal entities and departments concerning issues of mutual concern. To the extent possible, ORACBA has responded to requests for assistance of this type.

ORACBA Roles and Responsibilities in Agricultural Biotechnology

ORACBA is not within a USDA mission area. The function of the office is primarily oversight, and secondarily guidance, in meeting the Department's obligations for risk assessments in support of major rules. Thus, the office has no role or responsibility specific to biotechnology *per se*, however, the office will review any major rules concerning biotechnology.

- *Activities, programs, or services that ORACBA is performing now that are affected by biotechnology or that support the development, application or regulation of biotechnology by ORACBA.* To date, USDA has not proposed major rules (i.e., rules having as a primary focus to regulate risks to human health, human safety, or the environment with an annual economic impact of at least $100 million) for biotechnology. ORACBA is represented on the USDA Biotechnology Coordinating Committee (BCC) and provides guidance on information needed to make risk-based decisions regarding biotechnology.

- *Activities, programs, or services that are not currently being done that ORACBA may need to address within the next 5 years.* Unless ORACBA's statutory authority changes in some unexpected way, the office will not be extensively involved in activities extending beyond the current analytical review function. If any USDA agency proposes a major rule for biotechnology, that agency will be required to conduct a risk assessment as part of the regulatory impact analysis. ORACBA will provide guidance as needed for the risk assessment, and will have responsibility for assuring a thorough evaluation of the scientific basis for the rule. The effectiveness and timeliness with which ORACBA will guide and review risk assessments and review biotechnology-related rules will depend directly on the number of major rules proposed for all mission areas in USDA, not just biotechnology. Rule-making for biotechnology will attract considerable attention from the public and could be controversial. For several controversial issues, ORACBA has been asked to review risk assessments associated with non-major rules. A significant increase in regulatory activity, major or not, in *any* area requiring ORACBA's guidance and review could have an adverse effect on our ability to respond rapidly, assuming current staffing and budget.

  In the event of major rule-making by USDA for agricultural biotechnology, ORACBA would need to begin planning ahead of time for the required risk assessments. This would require a focused effort, with interagency participation, to develop frameworks for "life-cycle risk assessments" that identify, characterize, and to the extent possible quantify risks to human health and safety, animal and plant agricultural resources, and the environment at large, from the time biotechnological products are introduced, through handling and consumption, to disposal of the waste material. This difficult task would be necessary before the statutory requirement for risk assessment can be met.